Medical Policy
Sacral Nerve Neuromodulation/Stimulation

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- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
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Policy Number: 153
BCBSA Reference Number: 7.01.69
NCD/LCD: National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18)

Related Policies
Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, #470
Biofeedback as a Treatment of Urinary Incontinence, #173
Transanal Radiofrequency Treatment of Fecal Incontinence, #309
Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, #523
Percutaneous Tibial Nerve Stimulation, #583
Biofeedback as a treatment of Fecal Incontinence or Constipation, #308

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Urinary Incontinence and Non-obstructive Retention
A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered MEDICALLY NECESSARY in patients who meet ALL of the following criteria:
   1. There is a diagnosis of at least one of the following:
      a. Urge incontinence
      b. Urgency-frequency syndrome
      c. Non-obstructive urinary retention
      d. Overactive bladder AND
   2. There is documented failure or intolerance to at least two conventional conservative therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy) AND
   3. The patient is an appropriate surgical candidate AND
   4. Incontinence is not related to a neurologic condition.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered MEDICALLY NECESSARY in patients who meet all of the following criteria:
   1. All of the criteria in A (1-4) above are met.
   2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.
Other urinary/voiding applications of sacral nerve neuromodulation are INVESTIGATIONAL, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction.

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members**

**Fecal Incontinence**

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be MEDICALLY NECESSARY in patients who meet all of the following criteria:
   1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth.
   2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy
   3. The patient is an appropriate surgical candidate.
   4. The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease.
   5. Incontinence is not related to a neurologic condition.
   6. The patient has not had rectal surgery in the previous 12 months, or in the case of cancer, the patient has not had rectal surgery in the past 24 months.

B. Permanent implantation of a sacral nerve neuromodulation device may be MEDICALLY NECESSARY in patients who meet all of the following criteria:
   1. All of the criteria in A. 1-6 above are met.
   2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hour.

Sacral nerve neuromodulation (SNM) in the treatment of chronic constipation or chronic pelvic pain is INVESTIGATIONAL.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all three indications:
- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.
- Patient must have had successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

*National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18)*
Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<tr>
<td>Medicare PPO BlueSM</td>
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</tbody>
</table>

CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrodes; sacral nerve (transforminal placement)</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
</tr>
<tr>
<td>95971</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
<tr>
<td>95972</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
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HCPCS Codes

<table>
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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
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The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>596.51</td>
<td>Hypertonicity of bladder</td>
</tr>
<tr>
<td>787.60</td>
<td>Full incontinence of feces</td>
</tr>
<tr>
<td>788.20</td>
<td>Retention of urine, unspecified</td>
</tr>
<tr>
<td>788.21</td>
<td>Incomplete bladder emptying</td>
</tr>
<tr>
<td>788.29</td>
<td>Other specified retention of urine</td>
</tr>
<tr>
<td>788.30</td>
<td>Urinary incontinence, unspecified</td>
</tr>
<tr>
<td>788.31</td>
<td>Urge incontinence</td>
</tr>
<tr>
<td>788.33</td>
<td>Mixed incontinence (male) (female)</td>
</tr>
<tr>
<td>788.39</td>
<td>Other urinary incontinence</td>
</tr>
<tr>
<td>788.41</td>
<td>Urinary frequency</td>
</tr>
<tr>
<td>788.63</td>
<td>Urgency of urination</td>
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</tbody>
</table>

### ICD-10 Diagnosis Codes

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<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>N32.81</td>
<td>Overactive bladder</td>
</tr>
<tr>
<td>N39.41</td>
<td>Urge incontinence</td>
</tr>
<tr>
<td>N39.46</td>
<td>Mixed incontinence</td>
</tr>
<tr>
<td>N39.491</td>
<td>Coital incontinence</td>
</tr>
<tr>
<td>N39.492</td>
<td>Postural (urinary) incontinence</td>
</tr>
<tr>
<td>N39.498</td>
<td>Other specified urinary incontinence</td>
</tr>
<tr>
<td>R15.9</td>
<td>Full incontinence of feces</td>
</tr>
<tr>
<td>R32</td>
<td>Unspecified urinary incontinence</td>
</tr>
<tr>
<td>R33.0</td>
<td>Drug induced retention of urine</td>
</tr>
<tr>
<td>R33.8</td>
<td>Other retention of urine</td>
</tr>
<tr>
<td>R33.9</td>
<td>Retention of urine, unspecified</td>
</tr>
<tr>
<td>R35.0</td>
<td>Frequency of micturition</td>
</tr>
<tr>
<td>R39.14</td>
<td>Feeling of incomplete bladder emptying</td>
</tr>
<tr>
<td>R39.15</td>
<td>Urgency of urination</td>
</tr>
</tbody>
</table>

**Description**

Treatment using sacral nerve neuromodulation (SNM), also known as indirect sacral nerve stimulation (SNS), is one of several alternative modalities for patients with fecal or urinary incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (eg, prompted voiding) and/or pharmacologic therapies. Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to completely empty the bladder of urine. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.
The SNM device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4 to 7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. These include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to further refine patient selection.

The permanent device is implanted with the patient under general anesthesia. An incision is made over the lower back, and the electrical leads are placed in contact with the sacral nerve root(s). The wire leads are extended through a second incision underneath the skin, across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for 1 to 2 seconds.

### Summary
Sacral nerve neuromodulation (SNM), also known as sacral nerve stimulation (SNS), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This policy addresses use of SNM in the treatment of urinary or fecal incontinence, urinary or fecal nonobstructive retention, and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

There is sufficient evidence from randomized controlled trials to conclude that SNM improves the net health outcome in selected patients with urge incontinence, urgency-frequency, and nonobstructive urinary retention. In addition, the evidence is considered sufficient for SNM to be an option for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy. Not all patients will benefit, and the adverse event rate for this procedure is high. Patients should therefore be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.

Limited evidence reports that more patients have a positive stimulation trial when stage-1 surgery is used compared with percutaneous nerve evaluation and that most patients with a positive stage-1 test experience a reduction in symptoms after permanent implantation. This evidence does not determine with certainty that health outcomes are improved with the stage-1 trial stimulation. However, there is some supportive evidence and strong clinical support for surgical lead placement as an alternative to percutaneous test stimulation.

The literature on SNS for constipation and SNS for chronic pelvic pain remains insufficient to evaluate the effect of this technology on health outcomes.

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>2/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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</table>
Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


30. Leong RK, De Wachter SG, Nieman FH, et al. PNE versus 1st stage lined lead procedure: a direct comparison to select the most sensitive test method to identify patients suitable for sacral neuromodulation therapy. Neurourology and Urodynamics. Sep 2011;30(7):1249-1252. PMID 21404317